# **OPERATIONAL PROTOCOL**

# for the 1115 (HIV) Demonstration within the District of Columbia

# I. ORGANIZATION AND ADMINISTRATION

#### 1.1 Background on HIV Demonstration

Since protease inhibitors were first introduced in 1995, the lives of HIV-infected individuals with access to these medications have been prolonged and improved. Early treatment with highly active antiretroviral drug therapy (HAART) is the current standard of care for HIV-infected individuals according to U.S. Department of Health and Human Services treatment guidelines. Unfortunately, however, many people with HIV are uninsured or under-insured and cannot afford HAART, which costs approximately \$12,000 annually.

People with HIV generally do not qualify for Medicaid until they become disabled by HIV disease. Due to the disability requirement, very few DC residents with early HIV infection currently have Medicaid coverage. As an alternative, many individuals with early HIV infection obtain HAART therapy through the AIDS Drug Assistance Program (ADAP), a discretionary program funded through the Ryan White Care Act. Yet, ADAP does not cover many medical services its clients may need outside of HIV-related prescription drugs. Additionally, because ADAP is not an entitlement program, adequate funding is not guaranteed from year to year.

The District therefore plans to expand access to clinically recommended treatment for its low-income HIV+ population through an 1115-Demonstration program. This initiative, while jointly administered by Medical Assistance Administration (MAA) and the HIV/AIDS Administration (HAA) of the D.C. Department of Health, is grounded in extensive community-based input and support. The D.C. Primary Care Association (DC PCA) has taken the lead role in coordinating community input and involvement.

## 1.2 Overview of Program

The DC Medical Assistance Administration (MAA) has designed the 1115 (HIV) Demonstration to achieve the following goals:

- Increase access to HAART therapy for people with early HIV infection, in accordance with DHHS treatment guidelines; and
- Enhance access to the full range of Medicaid benefits for as many of the District's HIV+ population currently at or below 100% of the federal poverty line as is possible given the constraints posed by the federal budget neutrality requirement.

<sup>&</sup>lt;sup>1</sup> Of course, some individuals with HIV (e.g., pregnant women) are categorically eligible for Medicaid independent of their HIV or disability status.

Further, this coverage Demonstration program addresses some of the barriers to clinically recommended treatment that currently exist within programs that finance HIV/AIDS care.

# 1.3 Organizational Structure

The Medical Assistance Administration (MAA) will oversee all aspects of the 1115 (HIV) Demonstration, and will largely provide programmatic and financial support to the HIV/AIDS Administration (HAA). The HIV/AIDS Administration will conduct specific tasks, including eligibility determinations and initial case management referrals. Please see Appendix A for the District's organizational charts. Additionally, the delineation of responsibilities between the agencies is further specified in a Memorandum of Understanding that all local parties have signed and is attached as Appendix B.

## 1.4 Data Systems

The District will rely on a new Single Point of Entry (SPE) system that will coordinate the application process for multiple HIV/AIDS service programs. The SPE system uses a common application for the ADAP, 1115 (HIV), 1115 (50-64), Ticket to Work Demonstration programs (see scope of work, which is attached at Appendix C, and the draft application form, which is attached as Appendix D). The operational aspects of this system are further detailed in Sections 2.2-2.4 below.

The District plans to use an administrative database stored at HAA under HAA security as the principal component of the SPE. For claims adjudication and expenditure reporting, MAA will rely on the Medicaid Management Information System (MMIS).

# 1.5 Reporting

The Medical Assistance Administration will report expected and actual claims and administrative cost data from MMIS via the CMS-64 and CMS-37. Additionally, MAA will provide the actual number of eligible member months for current law Medicaid eligibles with a diagnosis of HIV or AIDS and who are receiving drug therapy regimens through the DOH pharmacy network and a summary of 1115 (HIV) expenditures in its quarterly progress reports to the Centers for Medicare and Medicaid Services (CMS). Specifically, these reports shall include information regarding the estimated number of eligible member/months for current law Medicaid enrollees with a diagnosis of HIV or AIDS, including but not limited to those receiving drug therapy regimens through the Federal Supply Schedule. These reports will be submitted 60 days after the end of each quarter. Summary expenditure and enrollee data will be reported in both the annual reports and the final report (submitted at end of the first five years of the Demonstration). Additionally, the District will submit CMS-64.9WAIV and/or CMS-64.9WAIV.P to report expenditures subject to the budget neutrality cap. These reports will include total computable as well as federal/local breakdowns of expenditures.

Further, the District will submit quarterly progress reports that are due 60 days after the end of each quarter. The reports should include, as appropriate:

- a discussion of events occurring during the quarter that affect health care delivery, including enrollment and outreach activities;
- access to needed services;

- quality of care;
- complaints, grievances, and appeals to the District;
- the benefit package;
- services coordination under the demonstration;
- numbers of demonstration enrollees, which includes a breakdown of those new enrollees and those enrollees who converted from the non-demonstration Medicaid program after losing Medicaid eligibility; and
- other operational and policy issues.

The reports will include proposals for corrective action that address any problems identified in each report.

The District will submit a draft annual report documenting accomplishments, project status, quantitative findings, and policy and administrative difficulties no later than 120 days after the end of its operational year. Within 30 days of receipt of comments from CMS, a final annual report will be submitted. Finally, the District shall submit a draft final report CMS for comments no later than 90 days after the termination of the Demonstration.

The District will also engage in monthly calls with CMS staff during the first six months of program operation. Thereafter, progress calls will be held on a quarterly or as needed basis. During the remainder of the demonstration, progress calls will be held quarterly, however, all parties will be available for additional calls as merited.

# II. OUTREACH, INTAKE, AND ENROLLMENT

#### 2.1 Outreach

After consultation with local advocacy and provider organizations (see attached list), the District will rely on Ryan White-funded case managers to serve as the principal outreach agents for the 1115/TWWIIA programs. In this way, the District will be able to reach more isolated populations in a culturally and linguistically appropriate manner. This effort will complement the vast simplifications in the application process that the District is implementing. In these ways, the District will reduce system fragmentation and lower both the administrative and cultural barriers to program enrollment.

For the case managers, HAA and MAA have developed training curricula and materials that focus on the new SPE system and joint program application. These materials (Appendix E) are forthcoming and will be available prior to the readiness review site visit by CMS. A list of HIV-experienced providers (compiled by HAA, supplemented by a list of infectious disease specialists in Medicaid) will be included.

As outlined in the MOU (Appendix B), HAA will:

- Conduct pharmacist and clinical provider education regarding the operational details of new HIV pharmacy network, including the use of the Medicaid Point-of-Sale (POS) system and First Health Pharmacy Benefits Manager (PBM); and
- Conduct information campaign for case managers, clients, advocates, and providers regarding the operational details of the new HIV pharmacy network.

Given the assistance of the case managers and small size of the waiver, the District will not produce educational information for clients that is specific to the 1115 (HIV) Demonstration. Rather, the District will use the CMS-approved materials for its current Medicaid program. Conveniently, this option may also eliminate confusion as 1115 (HIV) Demonstration clients transition to current law Medicaid.

# 2.2 Eligibility/Intake

Eligibility for the 1115 (HIV) Demonstration will be limited to individuals who are:

## HIV-infected<sup>2</sup>

Enrollees must furnish (a) HIV antibody or other serological test results in order to establish their HIV-positive serostatus; (b) signed statement from medical provider explicitly indicating client's HIV status; or (c) signed statement from case manager indicating that the client was previously eligible for ADAP or other Ryan White-funded services.

#### at or below 100% of FPL

Gross income reflected in the documentation provided with the application must be lower than this income cutoff. The District will not apply any income disregards that exceed those in the mainstream Medicaid program.

#### have assets below the categorically-needy resource limit

Resources cannot not exceed the categorically needy resource limits as noted in the State Plan (i.e., \$2,600 for individuals and \$3,000 for couples).

#### not eligible for Title XIX or Title XXI

See discussion of the SPE system's "trigger-and-pend" approach below. Note: persons eligible for Medicaid under spend-down provisions will be enrolled in that program and not in the 1115 Demonstration.

not residing in long-term care, mental health or penal institutions.

The SPE system will serve as a central intake point for applications for most publicly funded HIV service programs in the District. As stated previously, it will rely on a single application to determine eligibility for the ADAP, 1115 and Ticket to Work Demonstrations.

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<sup>&</sup>lt;sup>2</sup> Note: documentation requirements in this regard are still being finalized.

Note: coverage will begin on the date of enrollment; no retroactive coverage shall be permitted for hospital services, though the Director retains discretion to extend retroactive coverage to other services.

# 2.3 "Trigger-and-Pend" Screening for Medicaid Eligibility

The SPE system allows applications to proceed for the Demonstration program unless (a) an eligibility worker confirms an individual's enrollment in Medicaid or (b) a trigger for Medicaid, S-CHIP, or 1115 (50-64) eligibility pends the application. Triggers for Medicaid, SCHIP, and 1115 (50-64) include:

- self-reported SSI income;
- 50-64 years of age;
- age over 65 (with sufficiently low income);
- SSDI (with sufficiently low income);
- history of SSI
- pregnancy; and/or
- children in household.

When an application is pended due to a trigger, an eligibility worker would confirm eligibility and enrollment in other public programs. Using manual features in the SPE system, the worker would make alternative program assignments if applicable.

The decision rules behind eligibility determinations (Appendix C) reflect the decision to expand access to the maximal extent possible. Accordingly, applicants who indicate possible Medicaid eligibility will be referred to the DC Income Maintenance Administration (IMA).

As part of the applications, Demonstration applicants must sign an agreement that allows the District to move them between eligibility categories (e.g., 1115 HIV and 50-64, Ticket to Work, Medicaid). The District will change eligibility codes as appropriate and inform the affected beneficiaries in a timely manner. Because the scope of services is identical under all the codes, there will be no disruption in their enrollment or in continuity of care. To ensure successful transitions, the District will periodically review cases for Title XIX or XXI eligibility. To accomplish this, the District proposes creating utilization and other "prompts" for such reviews when the enhanced MMIS and case management systems are operational.

#### 2.4 Enrollment

The SPE will automatically perform eligibility determinations for all programs, enroll clients appropriately, and generate Notices of Action to clients. If information is missing, the SPE will generate letters requesting the information from the client and case manager (if one is indicated); once the information is received, the SPE will render a final eligibility determination. Demonstration enrollees will also receive a Medicaid packet virtually identical to that sent to all new Medicaid clients.

With regard to the 1115 (HIV) Demonstration, the District expects that the number of applications received from individuals <u>and</u> case managers (unless explicitly prohibited by the applicant) will exceed the enrollment ceiling prior to implementation. If this occurs, the HAA Waiver Unit will randomize eligible individuals and enroll applicants up to the enrollment ceiling. This random order of remaining clients will be used to create the waiting list's order of persons who will be enrolled in the Demonstration as slots become available. Additional slots can become available through initial Demonstration enrollees' disenrollment from the Demonstration (e.g. relocation, death, or failure to meet program eligibility requirements at redetermination) and through determination that the Demonstration enrollee has become eligible for current law Medicaid coverage.

We note the inherent bias in only including complete applications in the pool from which enrollees will be drawn. Some case managers or similar providers may be more proficient at completing Medicaid forms and may be better able to ensure the completeness of their clients' applications. For this reason, the District will conduct intensive training with case managers as to the enrollment process. Further, we have developed a clear, minimally-intrusive application (see Appendix D), which we hope will be easy for applicants <u>and</u> case manager (unless explicitly prohibited by the applicant) s to complete. As indicated in the attached application, the applicant's signature is required to indicate consent.

## 2.5 Referrals to Providers

The District will seek to connect Demonstration enrollees to primary care providers in the current fee-for-service (FFS) Medicaid network. However, the District cannot yet directly refer individuals to specific providers who are "HIV-experienced." A list of Ryan White providers will be provided to all case managers. The current list of these providers is included in the training curricula in the forthcoming Appendix E. Cognizant of this limitation, we developed the referral plan outlined below.

For all Demonstration applicants who do not indicate a case manager: after receiving the application, the District will mail to Demonstration applicants a referral list of RWCA case management providers and encourage the applicants to make an appointment. A second referral will be made when the Notice of Action is sent to applicants:

• For those enrolled in the 1115 (HIV) Demonstration and who have a case manager: As with existing Medicaid FFS clients, 1115 (HIV) Demonstration enrollees have their choice of Medicaid providers. Given the importance of selecting an HIV-experienced provider, the District will rely on RWCA case managers to refer to HIV-experienced physicians. These case managers already maintain a list of such providers, and the District will repeatedly emphasize the importance of such referrals during the case manager trainings. Further, MAA will mail 1115 (HIV) Demonstration enrollees a list of

Administration will update the 1115 Operational Protocol to reflect any future changes in this regard.

<sup>&</sup>lt;sup>3</sup> The District will use the random number generator in Excel to randomize clients. Numbers issued will be real numbers between 0 and 100,000. The District will then rank clients in ascending order and enroll them accordingly. 
<sup>4</sup> Unfortunately, MAA cannot make a direct referral to "HIV-experienced" physicians at this time unless we formally define this provider category in the State Plan and local regulations. The Medical Assistance

Ryan White HIV-experienced physician and clinic providers and Board-certified infectious disease specialists.

# • For those enrolled in the 1115 (HIV) Demonstration but who do not indicate a case manager:

The District will again refer all such Demonstration enrollees to Ryan White case management providers; these case managers may refer these enrollees to providers with substantial clinical experience with HIV/AIDS. This effort is consistent with the District's objective to ensure all Demonstration enrollees receive HIV case management and other supplemental services not presently covered by Medicaid. MAA mail to Demonstration enrollees a list of Ryan White HIV-experienced physician and clinic providers and Board-certified infectious disease specialists.

• For those on the waiting list or who are ineligible for the 1115 (HIV) Demonstration: MAA may elect to mail them a list of appropriate RWCA service providers; these applicants will also be enrolled in the ADAP program if they are eligible.

## 2.6 Redeterminations

Redeterminations will be conducted on an annual basis following the date of initial enrollment. Notices of redetermination will be sent to Demonstration enrollees and the case manager (if one is indicated). The redetermination form (to be developed as a collaborative effort between MAA and HAA) will be included in this mailing.

## 2.7 Informed Consent

Each enrollee will fill out and sign an informed consent form at time of application. Applicants shall certify:

- My participation is voluntary;
- Enrollment in the Medicaid Demonstrations are limited, and if the programs are already full at the time of my application I will be placed on a waiting list;
- If during the course of my enrollment in this program I become eligible for Title XIX or XXI (Medicaid/Healthy Families), I will be enrolled in the District Medicaid program in such a way that does not disrupt my continuity of care;
- DC MAA/HAA officials may contact my case manager to discuss information relevant to my application;
- DC MAA/HAA officials may verify the information on this form; and
- DC MAA/HAA officials may contact my insurance company to verify my coverage.

Enrolling in the 1115 HIV Demonstration, or being placed on the waiting list, is conditioned on these certifications. The District shall not enroll any individuals in the Demonstrations who fail to complete these certifications.

## 2.8 Confidentiality

The District will maintain the same standards of confidentiality for patient information as it maintains in the regular Medicaid program. Additionally, the eligibility data will be maintained

in a secure facility alongside the District ADAP data. Each agency that will collect and utilize information will be adhering to their own particular confidentiality standards for data collection and maintenance. These agencies include the Medical Assistance Administration, HIV/AIDS Administration, and Income Maintenance Administration.

# **III.** Enrollment Ceiling

## 3.1 Enrollment Ceiling Initiation and Adjustment

Enrollment ceiling figures are derived from an analysis of average wholesale, DC Medicaid, and Department of Defense (DoD) prices for selected HIV medications, grouped into three categories: Protease Inhibitors, Nucleoside Analogues (NRTIs), and Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs). AWP prices used in the analysis are from the 2001 Red Book while DoD prices are for 6/21/00-6/28/01. The cost to DC Medicaid was calculated based on the following formula: AWP – (.25\*AWP). The use of DoD prices generates a saving of approximately 22% over DC Medicaid. The District will enroll applicants on a first-come basis until the enrollment ceiling is reached.

See Appendix F for specific calculations and assumptions.

#### 3.2 Demonstration Enrollee Limit

The enrollment ceiling is only applicable to the 1115 (HIV) Demonstration, and will under no circumstances apply to the traditional Medicaid program.

Given the enrollment cap, individuals who are or subsequently become eligible for Title XIX or XXI may be transferred from the 1115 (HIV) Demonstration to these programs. Other 1115 (HIV) Demonstration enrollees will remain on the program as long as they are eligible.

## 3.3 Waiting List Mechanism

Should the number of applications received prior to the Demonstration's launch exceed the enrollment cap, the District will randomize the clients and enroll the number allowed by the enrollment cap (see Section 2.4). Individuals with complete applications who (a) applied for the Demonstration prior to launch and (b) were not initially enrolled due to the enrollment cap will be placed on the waiting list in random order.

The District will mail quarterly statements (according to confidentiality standards) as to each individual's standing on the waiting list. Six months following the implementation of the 1115 (HIV) Demonstration, the District will use program experience to estimate turnover in the 1115 (HIV) Demonstration. The District will indicate the projected time for entrance in the quarterly mailings.

When the District can enroll an individual from the waiting list, the Demonstration unit will send a Notice of Action to the client <u>and</u> case manager (unless explicitly prohibited by the applicant). That individual will have up to 30 days to confirm enrollment. If confirmation is not received within 30 days, another client will be invited to enroll. If such confirmation is received after 30 days but before 90 days, the original client will be moved to the top of the waiting list. Clients

who return confirmation after 90 days must reapply. The District reserves the right to vary these provisions in extraordinary circumstances (e.g., 120-day incarcerations).

# IV. Benefit Package

#### 4.1 Services

The District proposes to offer the full array of Medicaid benefits to all 1115 (HIV) Demonstration enrollees. Coverage includes laboratory and diagnostic services, pharmacy benefits, hospital care, physicians' services, mental health and substance abuse services, medical equipment and supplies, and transportation. Additionally, Ryan White case management services would be available to 1115 (HIV) Demonstration enrollees in the same manner presently made available to HIV-infected Medicaid beneficiaries. We reference the State Plan and supporting materials for additional detail in this regard.

## 4.2 Coordination of Services

This information will be included in the attached training curricula for case management providers (Appendix E).

#### 4.3 Pharmaceutical Distribution

Demonstration enrollees must obtain HIV medications at those pharmacies within the DOH pharmacy network. The DOH Pharmacy Warehouse will (1) accept orders for the medications from the participating pharmacies; (2) purchase the medications and accept delivery; and (3) distribute the medications to the network pharmacies. The system is a "just-in-time" delivery system, which allows both the Warehouse and the pharmacies to receive drugs within several days of the initial order.

The DOH HIV Pharmacy Network Request for Proposals (Appendix G) establishes minimum geographical access standards within the District. Specifically, each vendor must:

- Maintain at least fourteen (14) Medicaid-participating pharmacies within the District as access points; and
- Maintain at least two (2) participating Medicaid-participating pharmacies geographically located in Wards 7 and 8.

In this way, clients within the 60-square-mile area of the District will be adequately served, with all potential clients residing less than one mile from participating pharmacy. Based on preliminary data, the District expects that the pharmacy network may include greater than 50% of the current Medicaid antiretroviral volume and a larger share of the ADAP pharmacy volume. Thus, many if not most clients will retain their current pharmacy provider and others will be able to switch to nearby pharmacies.

Note: the District proposes to offer access to the same open formulary currently available to Medicaid beneficiaries. When beneficiaries go to obtain antiretroviral medication from a participating pharmacy, they may also access all other Medicaid prescriptions from that location.

## V. PROVIDER NETWORK AND ACCESS

#### 5.1 Provider Network

As with Medicaid FFS clients, 1115 (HIV) Demonstration enrollees have their choice of Medicaid providers. Noting the importance of selecting an experienced provider, we outlined in Section 2 above the referral mechanism of applicants/enrollees to RWCA case managers.

Given the relatively small number of 1115 (HIV) Demonstration enrollees relative to the District's overall Medicaid program (125,000-137,000 total clients), the addition of the Demonstration population will not overtax the existing provider network. The District has and continues to submit regular provider network data to CMS; this information on District Medicaid providers is equally applicable to the Demonstration.

#### 5.2 Educational Outreach to Provider Community

This information will be included in the training curricula for case management providers (see Appendix E). The District will use ongoing meetings of the HIV Subcommittee to inform physicians and clinics about the Demonstration.

Pursuant to HRSA and CMS guidance, the Medical Assistance Administration is engaged with the HIV/AIDS Administration in an effort to increase the number of RWCA providers with Medicaid provider agreements. Attached is a HAA prepared list of Medicaid-certified HIV-experienced physicians for RWCA case management beneficiaries. This initiative has been included as a component of the scope of work in the Phase II technical assistance contract for the 1915(c) waiver development. While this initiative is separate from the 1115 (HIV) Demonstration, it can only serve to increase the number of and improve client access to HIV-experienced providers in the Medicaid network.

#### 5.3 Americans with Disabilities Act

The scope of the District's provider monitoring regarding the provision of accessible services to disabled enrollees will include 1115 (HIV) Demonstration enrollees.

#### 5.4 Cultural Competency

Leveraging the cultural strengths and language abilities of the RWCA case managers, the District will ensure that potential enrollees or enrollees in the 1115 (HIV) Demonstration receive linguistic and culturally appropriate services.

#### 5.5 Continued Access

The District will ensure that the access standards for 1115 (HIV) Demonstration enrollees will remain in place, in the event of changes in the delivery system network, including the enrollment of its Medicaid population into managed care.

## VI. GRIEVANCE AND APPEAL PROCESS

#### 6.1 Eligiblity Grievances

Neither the TWWIIA nor the 1115 HIV Demonstrations constitute an entitlement to coverage for

all eligible persons or for the duration of eligibility for enrollees. These programs may be terminated at any time by the Centers for Medicare and Medicaid Services (CMS) or the District, though both entities would assist in appropriate transition planning.

Given this distinction between the Demonstrations and the current law (Title XIX and XXI) Medicaid programs, the District will not rely on the grievance procedures under 42 CFR 431 for eligibility questions. Rather, individuals may file eligibility grievances in writing with the Medicaid Director (known locally as the Senior Deputy Director for Medical Assistance Administration), who at his/her discretion, will forward appeals to the Chief of Health and Support Services within the HIV/AIDS Administration. The HIV/AIDS Administration will communicate a final ruling within thirty (30) days of receiving the complaint. The applicant may then appeal to the Senior Deputy Director for Health Promotions. Individuals will be informed of their rights in the relevant notices of action and grievance correspondence from the Department of Health.

# 6.2 Non-eligiblity Grievances

For non-eligiblity grievances, individuals may access the Fair Hearings process and follow the normal protocol for Medicaid appeals.

## VII. Quality Assurance

#### 7.1 Monitoring Plan

The District's monitoring plan will rely on the Automated Client Eligiblity Determination System (ACEDS) as well as intake data, case file review, and enrollee surveys. To facilitate monitoring and evaluation, the District will create a new eligibility category within the ACEDS for Demonstration enrollees. This will enable the District to more easily track individuals and simplify the data gathering process. Data for 1115 (HIV) Demonstration enrollees will be compared to data from the ADAP, regular Medicaid and the Ticket to Work Demonstration enrollees. To ensure that clients receive optimal care, MAA will incorporate quality assurance activities into the health care delivery and administrative system.

With regard to the monitoring plan, the MAA will track program enrollees' utilization of benefits and services. Staff members at MAA (or MAA contractors) will focus on identifying trends in prescription drug access and utilization and diagnostic service utilization as well as assess the problems noted by case managers and other program staff via data analyses and periodic focus groups. The District's new MMIS redevelopment contract with ACS Government Services (formerly ConsulTech) presents several opportunities in this regard. The development of the MAA data warehouse will allow more ready extraction of recent claims data for comparative purposes. Finally, staff from HAA and MAA will augment the claims monitoring with ongoing discussions with case managers, eligibility workers, and advocacy coordinators.

Further discussion of the District's quality assurance plan with respect to HIV/AIDS is included as Appendix I.

#### 7.2 Enrollee Survey

Given the practical and methodological complications of administering a survey with this population, the District shall satisfy the survey requirement by using unstructured group interviews to assess client satisfaction. The qualitative data gathered in these exercises will complement the clinical and demographic data available within the SPE and the administrative claims data within the MMIS. Please see Appendix I for further information regarding the District's Quality Assurance plan and activities.

# 7.3 Grievance and Appeals

The District will monitor the grievance and appeal process to ensure that enrollee concerns are resolved in a timely fashion, confidentiality is protected, and coordination between providers and the District is occurring in an efficient and effective manner. Further, the District will make every effort to inform applicants and enrollees of their rights through information transmitted in the Notices of Action. The District will include information on informal complaints, formal grievances, appeals and problem resolution in its quarterly progress notes to CMS.

# 7.4 Antiretroviral Therapy Data

The District proposes to report data on pharmacy utilization and trends using a modification of the methods developed by The Lewin Group and The Kaiser Family Foundation. We note that this approach is perhaps the most developed of the available research methods. To this end, the District has refined the methods employed by Kaiser and Lewin; these are detailed in the separate HIV research scope of work (Appendix H). Also, it may be feasible in future to use Point-of-Sale data from the Pharmacy Benefits Manager (in this case, First Health) to supplement these analyses. The District will pursue these and other options going forward and will submit more detailed plans in the forthcoming Evaluation Protocol document (see 7.6).

# 7.5 Additional Quality Assurance

The quality assurance requirements under the Title XIX and XXI programs, including oversight be Peer Review Organization/Quality Improvement Organization shall apply to providers that bill for services rendered to Demonstration enrollees.

# 7.6 Data Evaluation and Continuous Quality Improvement Plan

Plans for continuous quality improvement (CQI) activities are included in Appendix I. The results of these activities will serve as the basis for further quality improvement initiatives for the duration of the Demonstration. Additionally, the District plans to:

- Continue analyses of historical (or benchmark) data as contained in Appendix H;
- Assess the results of this and other studies in order to inform the design of the federally-funded evaluation for the Demonstration; and
- Incorporate into the evaluation and CQI program the results of Drug Utilization Review activities.

With respect to the Scope of Work for HIV Research Project, we note that this effort is jointly funded by the District, the DC Primary Care Association (under a Robert Wood Johnson grant) and the DC AIDS Partnership. This unique research collaboration between government, advocacy group, and philanthropic representatives builds on prior analyses funded by the Kaiser

Family Foundation and conducted by The Lewin Group. A draft report is expected in early FY 2003.

The District will cooperate fully with the federal contractor (i.e., Heath Economics Research) in planning and executing the evaluation protocol. Per agreement with CMS, this evaluation will satisfy the evaluation requirement in the Terms and Conditions for both the 1115 (HIV) Demonstration and the Ticket to Work Demonstration to Maintain Independence and Employment.

## **APPENDICES**

- A. Organizational Chart
- B. Inter-Agency Memorandum of Agreement
- C. Scope of Work and Proposed Business Logic for SPE (three separate documents)
- D. Application and Enrollment Forms (including draft application and proposed Notices of Action)
- E. Training Curricula for Case Management Providers
- F. Enrollment Cap Estimates and Supporting Analyses
- G. DOH HIV Pharmacy Network RFP
- H. Scope of Work for HIV Research Project
- I. Continuous Quality Improvement Plan